## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PCT NATIONAL STAGE APPLICATION OF

ART UNIT: 16251625

LOHSE, OLIVIER ET AL.

EXAMINER: SEAMAN, D

MARGARET M

INTERNATIONAL APPLICATION NO: PCT/EP2004/003479

FILED: APRIL 01, 2004

U.S. APPLICATION NO: 10/550621

35 USC §371 DATE: NOVEMBER 03, 2005

FOR: PROCESS FOR THE PREPARATION OF 5-(HALOCETYL)-8-

(SUBSTITUTED OXY)-1H)-QUINOLIN-2-ONES

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

### APPLICATION FOR PATENT TERM ADJUSTMENT-POST-GRANT

Sir:

In accordance with 37 C.F.R. § 1.705(d), Applicant hereby applies for patent term adjustment under 35 U.S.C. § 154(b) of 933 days. This application is being filed within two months of the date the patent issued, as required by 37 C.F.R. § 1.705 (d).

#### I. Fee

As required by 37 C.F.R. § 1.705(b)(1), please charge Deposit Account No. 19-0134 for \$ 200.00 to cover the required fee (as defined in 37 C.F.R. § 1.18(e)). Please charge any deficiencies or any additional fees due in response to this request to Deposit Account 19-0134.

### II. Statement of the Facts Involved

# A. Correct Patent Term Adjustment

Applicant received the Issue Notification on October 20, 2009. United States Patent No. 7,605,267 issued on October 20, 2009, indicating a patent term adjustment of 540 days.

Patentee has calculated a patent term adjustment of 933 days based on the following facts:

Case Law

In Wyeth v. Dudas, 2008 U.S. Dist. LEXIS 76063 (D.D.C. 2008), the District Court of the District of Columbia addressed the United States Patent and Trademark Office (USPTO) interpretation of 35 U.S.C. § 154(b)(2). The Court granted summary judgment in favor of Wyeth, determining that the USPTO misconstrued the first sentence of 35 U.S.C. § 154(b)(2)(A), and as a result, improperly denied Wyeth a portion of patent term to which Wyeth was entitled under 35 U.S.C. § 154.

In the opinion, the Court stated that "the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for 'A delay' or for 'B delay,' whichever is larger, but never A + B." However, Plaintiff Wyeth argued that the § 154(b)(1)(A) and § 154(b)(1)(B) period overlap only if they occur on the same calendar day or days. The Court determined that Wyeth's construction of § 154(b)(2) was correct.

Simply put, the holding of the Court is that the excluded overlap recited in the first sentence of 35 U.S.C. § 154(b)(2)(A) only occurs if a 35 U.S.C. § 154(b)(1)(A) period and a 35 U.S.C. § 154(b)(1)(B) period run concurrently. As such, a patent holder is entitled to recoup the 35 U.S.C. § 154(b)(1)(A) period that falls outside of the 35 U.S.C. § 154(b)(1)(B) period in addition to the 35 U.S.C. § 154(b)(1)(B) period itself.

#### **Relevant Dates**

The above identified application has an actual filing date of September 23, 2005 and a 35 U.S.C. §371 filing completion date of November 3, 2005.

The first Office Action, was mailed on September 24, 2008, resulting in a PTO delay of 630 days beyond the 14 months provided by 35 U.S.C. §154(b).

A Response to Office Action was filed by Patentee on March 24, 2009, resulting in an applicant delay of 90 days.

A Notice of Allowance was mailed June 12, 2009.

The issue fee was paid September 10, 2009.

The patent issued October 20, 2009.

Accordingly, the total PTO adjustment based on delay under 35 U.S.C. § 154(b)(1)(A) is 540 days.

The 35 U.S.C. § 154(b)(1)(B) period for US Patent 7,605,267 began on September 23,

2008 (three years after the actual filing date of September 23, 2005) and ended on the date of

issuance, October 20, 2009. The 35 U.S.C. § 154(b)(1)(B) period is 393 days.

There was no 35 U.S.C. § 154(b)(1)(A) delay that occurred within this 35 U.S.C. §

154(b)(1)(B) period that should be excluded from the patent term adjustment calculation under

the holding of Wyeth v. Dudas.

Accordingly, the sum of the 35 U.S.C. § 154(b)(1)(B) and non-overlapping 35 U.S.C. §

154(b)(1)(A) delay is (540 + 393 days) = 933 days.

Under 35 U.S.C. § 154(b)(2)(C), the total period of PTO delay is reduced by the period of

applicant delay, which is 90 days.

Accordingly, the correct patent term adjustment for the above identified application is 933

days (the difference between the total period of PTO delay under 35 U.S.C. § 154(b)(1) and

applicant delay under 35 U.S.C. § 154(b)(2)(C)).

The PTA printed on the front of US 7,605,267 is only 540 days, which the USPTO is

presumed to have calculated using the method considered proper before the holding of Wyeth v.

Dudas. Applicants therefore respectfully request reconsideration of the PTA listed on the front

of US 7,446,175.

B. Terminal Disclaimer

The above-identified patent is not subject to a Terminal Disclaimer.

C. Reasonable Efforts

Any applicant delays under 37 C.F.R. § 1.704 are set forth above. There were no other

circumstances constituting a failure to engage in reasonable efforts to conclude processing of

examination of the above-identified application, as set forth in 37 C.F.R. § 1.704.

Respectfully submitted,

Novartis Pharmaceuticals Corporation One Health Plaza, Bldg. 101

East Hanover, NJ 07936

(862) 778-9273

Date: / jee Decelor Dez 9

Cozette McAvov Attorney for Applicant

Reg. No. 60,457